

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

#18
BP
5-7-03



In re application of:

Dane K. FISHER *et al.*

Appln. No.: 09/540,235

Filed: April 3, 2000

For: **Nucleic Acid Sequences from
Cyanidium caldarium and Uses
Thereof**

Art Unit: 1631

Examiner: Michael L. BORIN

Atty. Docket: 38-21(15749)B

Confirmation No.: 1048

APPELLANT'S AMENDED BRIEF

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Sir:

This is an Appeal from the Rejection of all claims pending in the above-described patent application. A Notice of Appeal was filed on November 12, 2002, and Appellant's Brief was filed January 21, 2003, at which time the statutory fee of \$320.00 for submitting an appeal brief was paid. This Amended Brief is submitted in response to the Office Communication mailed April 10, 2003 (Paper No. 17), which alleged that the Brief filed January 21, 2003, was non-compliant with 37 C.F.R. 1.192(c). *This Brief is submitted in triplicate.*

1. Real Party in Interest

The real party in interest is Monsanto Company, a Delaware corporation with offices at 800 North Lindbergh Boulevard, St. Louis, Missouri 63167.

2. Related Appeals and Interferences

The Applicants are unaware of any Appeals or Interferences related to this Appeal.

3. Status of Claims

Claims 1, 2, and 4-7 are pending. Claim 3 was canceled. Appellants appeal all of the rejections of claims 1, 2, and 4-7.

4. Status of Amendments

Applicants have not filed any responses subsequent to Final Rejection in this case.

5. Summary of Invention

The invention is directed to a substantially purified nucleic acid molecule having the nucleic acid sequence of SEQ ID NO. 1. Specification at page 12, lines 7-9. The present invention is also directed to a transformed cell having a nucleic acid molecule comprising a structural nucleic acid molecule comprising the nucleic acid sequence of SEQ ID NO: 1. Specification at page 12, line 21 through page 13, line 5.

6. Issues

The issues in this Appeal are:

- (a) whether claims 1, 2, and 4-7 are unpatentable under 35 U.S.C. § 101 for alleged lack of patentable utility due to its not being supported by either a specific and/or substantial utility or a well-established utility; and
- (b) whether claims 1, 2, and 4-7 are unpatentable under 35 U.S.C. § 112, first paragraph for alleged lack of enablement due to its not being supported by either a specific and substantial utility or, alternatively, a well-established utility.

7. Grouping of Claims

Patentability of claims 1, 2, and 4-7 is addressed together in Sections 8.A through 8.C below. A copy of the claims on appeal is attached hereto as Appendix A.

8. Argument

A. Summary of Appellant's Position

As the Supreme Court said in *Brenner v. Manson*, the "...basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility....where specific benefit exists in currently available form." 383 U.S. 519, 534-35, 148 U.S.P.Q. 689, 695 (1966). Applicants have met their part of the bargain – they have proven that the claimed nucleic acid molecules, in their current form, provide at least one specific benefit to the public, *e.g.*, use to identify the presence or absence of a polymorphism. This benefit is specific, not vague or unknown, and it is a "real world" or substantial benefit. Because the claimed nucleic acids provide at least this benefit, they satisfy the utility requirement of 35 U.S.C. § 101. Because the specification teaches how to make and use the claimed nucleic acids for the disclosed utilities, the enablement requirement of 35 U.S.C. § 112 has been met.

B. The Claimed Nucleic Acids Have Legal Utility

Pending claims 1, 2, and 4-7 were erroneously rejected under 35 U.S.C. § 101 because the claimed inventions were allegedly not supported by a "...specific, substantial, and credible utility...". Final Action mailed August 13, 2002 (Paper No. 14) ("Final Action"), at page 3. According to the Final Action, the disclosed uses "...are generally applicable to broad classes of this subject matter." Final Action at page 3.

This analysis misstates the nature of the asserted uses, ignores disclosed utilities, and misapplies the doctrine of "practical utility" developed by the courts after *Brenner v. Manson*. The "...threshold for utility is not high: An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit." *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999), *citing Brenner v. Manson*, 383 U.S. 519, 534 (1966). Furthermore, an invention need only provide one identifiable benefit to satisfy 35 U.S.C.

§ 101. *See Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983) (“...when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown...”).

The courts have expressed a test for utility that hinges on whether an invention provides an “identifiable benefit.” *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999), *citing Brenner v. Manson*, 383 U.S. 519, 534 (1966). For analytical purposes, the requirement for an “identifiable benefit” may be broken into two prongs: (1) the invention must have a specific, *i.e.*, not vague or unknown benefit, *In re Brana*, 51 F.3d 1560, 1565, 34 U.S.P.Q.2d 1436, 1440 (Fed. Cir. 1995); and (2) the invention must provide a real world, *i.e.*, practical or “substantial” benefit. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563, 39 U.S.P.Q.2d 1895, 1899 (Fed. Cir. 1996). A corollary to this test for utility is that the invention must not be “totally incapable of achieving a useful result,” *i.e.*, the utility must not be incredible or unbelievable. *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d 1401, 1412 (Fed. Cir. 1992).

The present specification describes many objectives that are met by the present invention. The Examiner acknowledged that the specification describes multiple utilities for the present invention, including “...markers, the isolation of polypeptides, hybridization probes, primers, the isolation of full-length cDNAs or genes, which would be used to make protein and optionally further usage for mapping...” Office Action mailed November 6, 2001 (Paper Number 9) (“Office Action”), at page 4. In addition to these utilities, the claimed nucleic acid molecules are useful for obtaining protein molecules, determining the presence and/or identity of polymorphisms, measuring the levels of an mRNA molecule in a sample, determining the corresponding DNA sequence on a physical or genetic map, probing for other molecules, generating primers, obtaining other nucleic acid molecules from the same species, obtaining related protein coding sequences, obtaining promoters and other flanking genetic elements, screening cDNA or genomic libraries, obtaining nucleic acid homologs, detecting and

characterizing gene expressing, etc. See Specification at pages 90-108, under the heading “Uses of the Agents of the Present Invention.” Any of these utilities alone is enough to satisfy Section 101. Because Applicants need only establish a single utility to satisfy 35 U.S.C. § 101, and have done so in the present case, the premise of the rejection under Section 101 is incorrect, and the rejection should be reversed.

**(1) The Claimed Nucleic Acid Molecules Provide A Specific Benefit, *i.e.*,
They Have Specific Utility**

Applicants have asserted that the claimed nucleic acid molecules¹ are themselves useful for utilities disclosed in the specification, *e.g.*, to detect the presence or absence of polymorphisms, and as hybridization probes for monitoring gene expression. Specification at page 92, line 19 through page 93, line 7 and at page 104, lines 8-15. The specification also discloses additional utilities for the claimed nucleic acid molecules, including as a probe for obtaining other nucleic acid molecules such as nucleic acid homologues. Specification at page 89, lines 14-19. For example, a nucleic acid molecule that encodes, in whole or in part, protein homologues of other organisms can be readily obtained by using the nucleic acid molecule of the invention to screen cDNA or genomic libraries for such a homologue. Specification at page 89, lines 14-19. Such a use as a screening assay has a legally sufficient utility.² Other utilities disclosed in the specification include use of the claimed nucleic acid molecules to measure the level of mRNA in a sample,³ and use as molecular markers.⁴

¹ It is irrelevant whether the corresponding mRNA or polypeptide have utility because Applicants are not relying on utility of the mRNA or polypeptide to establish utility of the claimed nucleic acid molecules.

² See, *e.g.*, MPEP § 2107 at page 2100-33.

³ It is standard practice to screen populations of nucleic acids with EST sequences, often attached to a microarray, without characterizing each and every target mRNA. Knowing that the gene corresponding to the claimed nucleic acid molecules is expressed under certain conditions or in certain tissues or at certain levels is in itself useful. For example, such information is useful to detect expression changes in traits of interest, *e.g.*, drought stress. Contrary to the Examiner's assertions, this use is not using the claimed nucleic acid molecules to identify a “real world” context of use.” See Final Action at page 3. It is a use of the claimed nucleic acid molecules in a real world context.

(a) Identifying the Presence or Absence of a Polymorphism

One of the utilities disclosed in the specification is use of the claimed nucleic acid molecules to identify the presence or absence of a polymorphism. Specification at page 92, lines 15-18. The Examiner argues that this utility, like all of the asserted utilities, is not specific or substantial, *see* Final Action at page 3, but does not provide any support (legal or factual) for the proposition that detection of polymorphisms is not a legal utility.

Many of the disclosed utilities in this case are directly analogous to the utilities of a microscope. An important utility of a microscope resides in its use to identify and characterize the structure of biological tissues in a sample, cell, or organism. Significantly, the utility of the microscope under 35 U.S.C. § 101 is not compromised by its use as a tool in this manner. Many of the disclosed utilities for the nucleic acid molecules of this invention are directly analogous to the utilities of a microscope, *i.e.*, the claimed nucleic acid molecules may be used to locate and measure nucleic acid molecules within a sample, cell, or organism. The Examiner denigrates this utility by asserting that these uses are not “useful” because a scientist would not know how to use the information gathered or the nucleic acid molecule being measured. *See* Final Action at page 3. However, the fact that, for example, a new and nonobvious microscope or screening assay can be used for learning about products or processes does not lessen the fact that such “tools” have legal utility. “Many research tools such as gas chromatographs, screening assays, and nucleotide sequencing techniques have clear, specific and unquestionable utility (*e.g.*, they are useful in analyzing compounds).” MPEP § 2107 at page 2100-33.

Use of the claimed nucleic acid molecules to detect the presence or absence of polymorphisms is no more legally insufficient than using a gas chromatograph to analyze the

⁴ One can use the claimed nucleic acid molecules to determine location of a corresponding DNA sequence on a physical map or genetic map location without knowing anything beyond the claimed sequence. The use of molecular markers is a practical activity in the development of nutritionally enhanced or agriculturally enhanced crops. Such markers are useful in, for example, genetic mapping or linkage analysis, marker-assisted breeding, physical genome mapping, transgenic crop production, crop monitoring diagnostics, and gene identification and isolation. As more markers are identified, genetic maps will become more detailed and it will be easier for plant breeders to breed for particular traits.

chemical composition of a gas – such use determines information about the gas, not the gas chromatograph. Even if the gas chromatograph detects the absence of a particular chemical element in the gas, that finding does not obviate the utility of the gas chromatograph itself. Information has been obtained about the gas.⁵ Likewise, the claimed nucleic acid molecules have utility even if the absence of a particular polymorphism is detected. Indeed, the absence of a polymorphism usefully demonstrates that the two (or more) populations being compared share a common genetic heritage.

The claimed nucleic acid molecules have been asserted to work for a specific, *i.e.*, not vague or unknown benefit – to identify the presence or absence of a polymorphism. This benefit is immediately realized directly from the use of the claimed nucleic acids, not from the use of other molecules. Such a proven use that provides an acknowledged known benefit to the public satisfies the utility requirement of 35 U.S.C. § 101.

(b) Source for Primers or as Probes for Other Molecules

Other uses for the claimed nucleic acid molecules are to define a pair of primers or as probes that may be used to isolate the homologue-encoding nucleic acid molecules from any desired species. Such molecules can be expressed to yield homologues by recombinant means. Specification at page 19, lines 3-5 and at page 89, lines 14-19. The Examiner suggests that these uses are not legal utilities because “Identifying and studying the properties of a protein itself or the mechanisms in which the protein is involved does not define a ‘real world’ context or use.” Office Action at page 5. This is not correct. The specification discloses that the claimed nucleic acid molecules can be used, via hybridization, in real world applications such as to isolate nucleic

⁵ For example, gas sampled from crude oil may be analyzed by gas chromatography for the presence or absence of chlorine, which is toxic to catalysts used in gasoline refining even in very low concentrations. The absence of a peak at the molecular weight of chlorine indicates the absence of chlorine in the sample being tested, thereby providing useful information (no chlorine is present, therefore the catalyst will not be destroyed) to the refinery manager. *See, e.g.*, U.S. Patent No. 6,133,740 entitled “Chlorine Specific Gas Chromatographic Detector.”

acid molecules of other species, plants or other organisms.⁶ Specification at page 89, lines 14-19. The Examiner has not provided any evidence that would reasonably suggest that this cannot be done, and so has not met the burden of proof required to establish a utility rejection. *See In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). *Accord In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975); *In re Langer*, 503 F.2d 1380, 1391, 183 U.S.P.Q. 288, 297 (C.C.P.A. 1974).

One illustrative example of a molecule that can be isolated using the claimed nucleic acid molecules is the promoter of the gene corresponding to the claimed nucleic acid molecules. Applicants have specifically disclosed that one use of the claimed nucleic acid molecules is to initiate a chromosome walk. Specification at page 90, lines 21 through page 91, line 20. The Final Action denigrates that utility when it asserts that it is a utility that is applicable to nucleic acids in general. Final Action at page 3, Office Action at page 5.

In short, the Examiner appears to be arguing that the utility is not a legal utility simply because other molecules can be used for the same purpose, *i.e.*, chromosome walks. That position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) (“An invention need not be the best or the only way to accomplish a certain result...”). Such an argument would imply that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.*, hitting golf balls. That position must be rejected as it requires reading “into the patent laws limitations and conditions which the legislature has not expressed,” a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty*, 447 U.S. 303, 308, 206 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 162 (1933).

⁶ Furthermore, one skilled in the art of hybridization and amplification understands how to design and utilize probes and primers to target a sequence of interest, and therefore it is not necessary for Applicants to provide a laundry list of each and every nucleic acid molecule that can be identified using the claimed nucleic acid molecules.

Moreover, it is factually incorrect that this use is not “specific” to the claimed nucleic acids. The claimed nucleic acid molecules provide a particularly appropriate and demonstrably useful starting point for a walk to isolate a promoter that is active in *Cyanidium caldarium*. A random nucleic acid molecule does not provide an equally good starting point to isolate such a promoter. Furthermore, even if a random nucleic acid molecule provided a better starting point than the claimed nucleic acid molecules, it would not obviate the utility of the claimed nucleic acid molecules. An invention may be “less effective than existing devices but nevertheless meet the statutory criteria for patentability.” *Custom Accessories, Inc. v. Jeffrey-Allan Indus.*, 807 F.2d 955, 960 n.12, 1 U.S.P.Q.2d 1196, 1199 n.12 (Fed. Cir. 1986).

The Examiner has failed to provide evidence, or even to suggest a reason for believing that the claimed nucleic acid molecules could not be so used. Accordingly, the assertion of this utility as a probe for other molecules or as a source of primers satisfies the requirements of 35 U.S.C. § 101. *See In re Brana*, 51 F.3d 1560, 1566, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995).

(1) The Claimed Nucleic Acid Molecules Provide Practical, Real World Benefits, i.e., They Have Substantial Utility

It appears that the Examiner is arguing that the disclosed uses are legally insufficient or “insubstantial” under 35 U.S.C. § 101, but such an argument has no basis in law. The touchstone of “substantial” utility is “real world” or “practical utility.” *See, e.g., Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563, 39 U.S.P.Q.2d 1895, 1899 (Fed. Cir. 1996). “ ‘Practical utility’ is a shorthand way of attributing ‘real world’ value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public.” *Nelson v. Bowler*, 626 F.2d 853, 856, 857, 206 U.S.P.Q. 881, 883 (C.C.P.A. 1980) (“tests evidencing pharmacological activity may manifest a practical utility even though they may not establish a specific therapeutic use”).⁷

⁷ *Accord Cross v. Iizuka*, 753 F.2d 1040, 1050, 224 U.S.P.Q. 739, 747-48 (Fed. Cir. 1985); *Rey-Bellet v. Engelhardt*, 493 F.2d 1380, 1383, 181 U.S.P.Q. 453, 454 (C.C.P.A. 1974).

There can be no question that one skilled in the art can use the claimed nucleic acid molecules in a manner which provides an immediate benefit to the public, for example to detect the presence or absence of polymorphisms. The detection of polymorphisms provides an immediate benefit to the public because, for example, it enables a plant breeder to determine the distribution of parental genetic material in the progeny of a cross. This information about a plant's genetic profile, like the information about a compound's pharmacological profile in *Nelson*, provides an immediate benefit and thus a practical utility to the public.

Quite apart from the detection of polymorphisms, there is also no question that the public has recognized the benefits provided by the claimed subject matter, and has attributed "real world" value to such nucleic acid molecules. The utility of ESTs is not merely an academic issue; the real world value of ESTs is self-evident from the growth of a multi-million dollar industry in the United States premised on the usefulness of ESTs. Like fermentation processes involving bacteria, ESTs and nucleic acid molecules with EST sequences are "industrial product[s] used in an industrial process – a useful or technical art if there ever was one." *See, e.g., In re Bergy*, 563 F.2d 1031, 1038, 195 U.S.P.Q. 344, 350 (C.C.P.A. 1977).

The market participants for EST products are primarily sophisticated corporations and highly knowledgeable scientists who are unlikely to pay for useless inventions. *Cf. Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 960, 220 U.S.P.Q. 592, 599 (Fed. Cir. 1983) ("People rarely, if ever, appropriate useless inventions"). Quite simply, the commercial value of ESTs is proof of their real world value and of the benefits they provide to the public. This evidence cannot be ignored. The patent system was created to serve and foster growth and development in the industrial arts. If the industries themselves recognize and appreciate the value of an invention, it is not for the Patent Office to say that they are mistaken.

(2) The Disclosed Utilities Are Credible to One of Skill in the Art

An assertion of utility must be accepted by the Examiner unless it would not be considered “credible” by a person of ordinary skill in the art. MPEP § 706.03(a)(1). Cases in which utility was found not to be credible are rare, and usually involve “hare-brained” utilities.⁸ A challenge to the credibility of a utility is essentially a challenge directed to operability, and such a challenge must be supported by a clear statement of “factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability.” *In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975); *see In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995); MPEP § 706.03(a)(1).

Applicants have explicitly identified specific and substantial utilities, not only in the specification, but in Applicant’s Response dated February 5, 2002 at page 5. “To violate [35 U.S.C.] 101 the claimed device must be totally incapable of achieving a useful result.” *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d 1401, 1412 (Fed. Cir. 1992). To date, the Examiner has provided no evidence that the claimed nucleic acid molecules will not work for the disclosed utilities. Unless and until the Examiner can prove that the claimed invention is wholly inoperative, the rejection must be withdrawn.

A. The Claimed Nucleic Acids Are Enabled by the Specification

The enablement of the claimed nucleic acid molecules has been challenged. Claim 1 was erroneously rejected as not enabled by the specification, because the claimed nucleic acid

⁸ Examples of incredible utilities are given in MPEP § 2107 at page 2100-33-34, and include:

an invention asserted to change the taste of food using a magnetic field (*Fregeau v. Mossinghoff*, 776 F.2d 1034, 227 U.S.P.Q. 848 (Fed. Cir. 1985)), a perpetual motion machine (*Newman v. Quigg*, 877 F.2d 1575, 11 U.S.P.Q. 1340 (Fed. Cir. 1989)), a flying machine operating on “flapping or flutter function” (*In re Houghton*, 433 F.2d 820, 167 U.S.P.Q. 687 (C.C.P.A. 1970)), a method for increasing the energy output of fossil fuels upon combustion through exposure to a magnetic field (*In re Ruskin*, 354 F.2d 395, 148 U.S.P.Q. 221 (C.C.P.A. 1966)), uncharacterized compositions for curing a wide array of cancers (*In re Citron*, 325 F.2d 248, 139 U.S.P.Q. 516 (C.C.P.A. 1963)), a method of controlling the aging process (*In re Eltgroth*, 419 F.2d 918, 164 U.S.P.Q. 221 (C.C.P.A. 1970)), and a method of restoring hair growth (*In re Ferens*, 417 F.2d 1072, 163 U.S.P.Q. 609 (C.C.P.A. 1969)).

molecules allegedly lack utility and therefore cannot be enabled. Final Action at page 4. This rejection has been overcome by the arguments stated above regarding utility because it is well-established law that “the enablement requirement is met if the description enables *any* mode of making and using the invention.” *Johns Hopkins University v. CellPro*, 152 F.3d 1342, 1361, 47 U.S.P.Q.2d 1705, 1719 (Fed. Cir. 1998) (emphasis added), quoting *Engel Indus. v. Lockformer Co.*, 946 F.2d 1528, 1533, 20 U.S.P.Q.2d 1300, 1304 (Fed. Cir. 1991). Unless and until the Examiner comes forth with evidence to rebut the objective truth of the utilities disclosed in the specification, this enablement rejection must be withdrawn as improper. *See In re Wright*, 999 F.2d 1557, 1561-62, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993); *Ex parte Lemak*, 210 U.S.P.Q. 306, 307 (Bd. App. 1981) (“pure conjecture” does not substantiate rejection for lack of enablement).

CONCLUSION

In view of the foregoing, it is respectfully requested that the Board of Patent Appeals and Interferences reverse the Rejections and that the subject application be allowed forthwith.

Respectfully submitted,

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by J.E. Cohan

Lawrence M. Lavin, Jr. (Reg. No. 30,768)
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Date: May 2, 2003

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APPENDIX A

1. A substantially purified nucleic acid molecule that comprises a nucleic acid sequence of SEQ ID NO: 1.
2. The substantially purified nucleic acid molecule according to claim 1, wherein said nucleic acid molecule encodes a *Cyanidium caldarium* protein or fragment thereof.
3. A transformed cell having a nucleic acid molecule which comprises:
 - (a) an exogenous promoter region which functions in said cell to cause the production of a mRNA molecule; which is linked to
 - (b) a structural nucleic acid molecule, wherein said structural nucleic acid molecule comprises a nucleic acid sequence of SEQ ID NO: 1; which is linked to
 - (c) a 3' non-translated sequence that functions in said cell to cause termination of transcription and addition of polyadenylated ribonucleotides to a 3' end of said mRNA molecule.
5. The transformed cell according to claim 4, wherein said cell is selected from the group consisting of an algal cell, a plant cell, a mammalian cell, a fungal cell, and an insect cell.
6. The transformed cell according to claim 4, wherein said cell is an algal cell
7. The transformed cell according to claim 6, wherein said cell is a *Cyanidium caldarium* cell.